

REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 188 and 191 are cancelled, claims 105, 180, 189, 190, 192 and 193 are amended and claims 209 and 210 are added, whereby claims 105-187, 189, 190 and 192-210 will be pending. Claims 105, 163, 180, 207 and 208 are independent claims. Support for the amended and new claims can be found throughout the present specification, the original claims and the drawings.

Applicants emphasize that the amendments to independent claims 105 and 180 are without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute these claims in their unamended form in one or more continuation and/or divisional applications.

Summary of Office Action

Applicants note with appreciation that the objection to claims 161 and 162 and the rejection of claims 141 and 199 under 35 U.S.C. § 112, second paragraph, as well as the previously applied art rejections in view of Kania, WO 01/60599 A1, have been withdrawn.

Claims 105-108, 121, 122, 139-141, 174, 176, 177, 179, 180-183 and 197-199 are newly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Juhasz, EP 0 099 758 (hereafter "JUHASZ").

Claims 105-116, 119, 124, 125, 128-136, 139-141, 147, 148, 163, 164, 174-186,

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188-191, 193-195 and 197-199 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2004/0241214 by Kirkwood et al. (hereafter "KIRKWOOD").

Claims 126, 127, 167, 192 and 206 remain rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over KIRKWOOD.

Claims 117, 118, 120-123, 142-146, 152-162, 165, 168, 169, 171-173, 187 and 200-205 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD.

Claims 137, 138 and 196 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of U.S. Patent No. 6,903,243 to Burton (hereafter "BURTON").

Claims 149-151, 170, 207 and 208 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of U.S. Patent No. 6,333,093 to Burrell et al. (hereafter "BURRELL").

Claims 105-208 remain provisionally rejected under the non-statutory doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-20 and claims 1-34 of copending Application Nos. 11/255,956 and 11/255,957.

Response to Office Action

Withdrawal of the rejections of record is respectfully requested, in view of the foregoing amendments and the following remarks.

Response to New Rejection of Claims under 35 U.S.C. § 102(b) over JUHASZ

Claims 105-108, 121, 122, 139-141, 174, 176, 177, 179, 180-183 and 197-199 are newly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by JUHASZ. The rejection alleges that JUHASZ teaches a multi-layered composite wound dressing comprising a semi-permeable membrane (second layer), a supporting and reinforcing permeable layer and a biodegradable tissue interface (first layer) with said permeable layer (preferably coated with silver) being located between the semi-permeable membrane and the biodegradable tissue interface.

Applicants respectfully submit that even if one were to share the Examiner's analysis of JUHASZ, this document does not anticipate the subject matter of any of the present claims. In this regard, it is noted that independent claim 105 submitted herewith recites, *inter alia*, that the first, liquid-permeable layer is an outermost layer and that a coating of an antimicrobial metal in elemental form as such is present between the first and second layers on at least one of the surfaces of the first and second layers. Even if one were to share the Examiner's opinion that the biodegradable tissue interface of the multi-layered composite wound dressing of JUHASZ corresponds to the first layer and the semi-permeable membrane of the wound dressing of JUHASZ corresponds to the second layer, the silver plating of JUHASZ would not be present on one of the surfaces of the first layer and/or on one of the surfaces of the second layer, but on the surface of the intermediate supporting and reinforcing permeable layer. For this reason alone, JUHASZ does not anticipate claim 105 or any of the claims dependent therefrom.

Further, even if one were to take the position that the intermediate supporting and

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reinforcing permeable layer of the composite of JUHASZ corresponds to the first layer of the composite of claim 105, JUHASZ would not anticipate claim 105 (or any of the claims dependent therefrom) for at least the reason that the supporting and reinforcing permeable layer is not an outermost layer (the permeable layer is sandwiched between the semi-permeable membrane and the biodegradable tissue interface).

Regarding independent claim 180 submitted herewith, Applicants note that this claim recites language from cancelled claim 191, which claim is not rejected over JUHASZ. Accordingly, this rejection is moot.

Applicants submit that for at least all of the foregoing reasons the rejection under 35 U.S.C. § 102(b) over JUHASZ is unwarranted, wherefore withdrawal thereof is respectfully requested.

Applicants emphasize that the amendments to independent claims 105 and 180 are not to be construed as Applicants' admission that any of the allegations regarding JUHASZ set forth in the present Office Action is of any merit. These amendments were made merely for the purpose of facilitating the prosecution of the present application and expediting the issuance of a patent with the claims submitted herewith.

Response to Rejection of Claims over KIRKWOOD/BURTON/BURRELL

The present Office Action essentially repeats the rejections of claims 105-207 under 35 U.S.C. § 102(e)/103(a) based on KIRKWOOD alone or in view of BURTON or BURRELL set forth in previous Office Actions. These rejections have already been addressed by Applicants in the responses to the previous Office Actions. Applicants

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comments in these earlier responses are expressly incorporated herein. Regarding the allegations set forth in sections 10 to 16 of the present Office Action, Applicants respectfully submit the following comments.

In response to the previous Office Action, Applicants amended independent claims 105, 163 and 180 to make it clear that the silver coating/layer recited therein is a coating/layer of elemental silver as such. The term “as such” is defined in paragraph [0068] of the present specification to mean “without any other materials”.

As explained by Applicants, the primary document relied on by the Examiner, i.e., KIRKWOOD, does not teach or suggest a coating of silver without any other materials. Particularly from paragraphs [0052] and [0053] of KIRKWOOD it is apparent that a coating of colloidal silver according to KIRKWOOD would not consist of colloidal silver without any other materials, but would comprise microparticles or microspheres loaded with colloidal silver. A specific example of these microparticles or microspheres is described in paragraph [0070] of KIRKWOOD, i.e., cross-linked gelatin microspheres having an effective minimum diameter of from about 0.4 mm to about 1 mm and containing 3% w/w of chlorhexidine antiseptic.

In response to Applicants’ amendments and arguments, in section 10 of the present Office Action it essentially is asserted that the definition of “as such” set forth in paragraph [0068] of the present specification is to be disregarded. In this regard, the Examiner relies on *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993), according to which limitations from the specification are not read into the claims.

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In this regard, Applicants respectfully submit that paragraph [0068] of the present specification recites not merely a limitation that is not reflected in the claims, but a definition of a term which is recited in the present independent claims. According to MPEP § 2111.01, “[w]hile the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning **unless** applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ... *MSM Investments Co. v. Carolwood Corp.*, 259 F.3d 1335, 1339-40, 59 USPQ2d, 1856, 1859-60 (Fed. Cir. 2001) ... It is only when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970)” (bold face provided).

Applicants submit that in view of the foregoing, the definition of the term “as such” provided in the present specification must not be disregarded when interpreting this term in the present independent claims. As pointed out above, KIRKWOOD does not teach or suggest a coating of elemental silver as such and for this reason alone fails to anticipate or render obvious, alone or in combination with any of the other documents relied on by the Examiner, the subject matter of any of the present claims.

Regarding the comments in the last three lines of section 10 of the present Office Action, Applicants respectfully submit that even if it is correct that “no exclusionary statements have been set forth in the instant claims to preclude additional materials being

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present in between the first and second layers” it is not seen how this affects the assessment of the patentability of the claimed subject matter in view of KIRKWOOD.

The relevant question in this regard is whether or not KIRKWOOD teaches or suggests the presence of a coating of elemental silver as such. The answer to that question is that KIRKWOOD clearly does not teach or suggest the presence of a coating of elemental silver as such, but may be considered to merely suggest (i.e., does not even exemplify) microparticles or microspheres loaded with colloidal silver. Neither KIRKWOOD nor any of the other documents relied on by the Examiner teaches or suggests that these loaded microparticles or microspheres can be replaced by colloidal (elemental) silver as such. It is emphasized again that the agent-loaded microparticles/microspheres of KIRKWOOD are an integral and critical part of the invention disclosed therein because they must be big enough to be held back by the wound contacting sheet in the dry state and must be small enough to pass through the opened or enlarged apertures of the wound contacting sheet in the presence of wound exudates.

In section 11 of the present Office Action it is alleged that “Applicant argues that the microparticles/microspheres are not capable of releasing the anti-microbial metal.” Applicants are unable find a corresponding statement in the response(s) to the previous Office Action(s), and neither has the Examiner indicated where a statement which could reasonably be interpreted in the way alleged by the Examiner can be found in Applicants’ response(s).

The remaining allegations set forth in sections 12 to 16 with respect to a combination of the teachings of KIRKWOOD and BURRELL have already been addressed

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in the responses to the previous Office Actions. For at least all of the reasons stated in these responses, Applicants respectfully disagree with the Examiner in this regard. At any rate, the rejections over KIRKWOOD in view of BURRELL relate exclusively to one specific aspect of the present invention, i.e., the provision of an additional coating/layer. As set forth above, the Examiner has failed to establish a *prima facie* case of obviousness with respect to the subject matter recited in independent claims 105, 163 and 180. Accordingly, the subject matter of the claims rejected over KIRKWOOD in view of BURRELL is patentable for this reason as well.

To sum up, for at least all of the reasons set forth above and in the responses to the previous Office Actions, withdrawal of all rejections of record is warranted and respectfully requested.

Applicants again respectfully request that the claim rejections under the doctrine of obviousness-type double patenting be held in abeyance until the Examiner has indicated allowable subject matter in this and the two copending applications.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

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Applicants point out that a Supplemental Information Disclosure Statement is being filed concurrently herewith. Accordingly, the Examiner is respectfully requested to indicate consideration thereof by returning a signed and initialed copy of the Form PTO-1449 submitted therein with the next official communication.

Respectfully submitted,
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September 7, 2006
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